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Are Health Care Providers Following Evidence-Based Practice Guidelines For The Screening, Diagnosis And Treatment Of Childhood Obesity?

Cara Harris

Thu Tran

TETANUS, DIPHTHERIA, AND PERTUSSIS SCREENING AND PERTUSSIS PREVENTION THROUGHOUT THE AGE SPAN

By

Cara Harris

Thu Tran

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Date: 12/12/13

Approved: _____
Supervising Professor/Committee Chair

Approved: _____
Committee Member

Approved: Sheila V. Adams
Committee Member

_____
Director of Graduate Studies

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—Cara Harris

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Cara Harris, RN, BSN

Thu Tran, RN, BSN

Mississippi University for Women, 2013

Supervising Faculty: Dr. Patsy Smyth, FNP, BC

Abstract

Pertussis, commonly called whooping cough, is a contagious disease, which has seen a substantial rise in epidemic proportions during 2011. The respiratory infection, which causes a severe uncontrollable cough in any age group, can cause severe complications in infants and elderly. The diphtheria toxoid and acelluar pertussis (Tdap) vaccine is the most effective protection strategy for preventing the disease. The purpose of this study was to determine if preteens and adults are screened and given the Tdap vaccine. A retrospective chart review was the design used to provide data for the research. The theoretical framework used for the research was the Health Promotion and Disease Prevention model by Nola J. Pender. Research questions included the following: Are preteens between the ages of 10 and 12 years screened and offered a Tdap vaccine? Are adults screened and offered the Tdap booster immunization for protection of pertussis? Several family practice clinics in Mississippi were the setting, and the target population was preteens between the ages of 10 and 12 years and adults over the age of 18 years. Fifty different charts from four different clinics were used for data collection. The analysis used to organize and interpret the data was frequency distribution, means, and standard deviation.

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CHAPTER I

Dimensions of the Problem

Pertussis, commonly called whooping cough, is one of the leading causes of vaccine preventable deaths despite the availability of a safe immunization. An average of 50 million cases occurs worldwide each year with 300,000 resolving in death. In the last 10 years there has been an increase in pertussis-related deaths in infants. In mid-2011, preteens and adolescents had a sustained epidemic increase in the spread of *Bordetella pertussis* or whooping cough (Debolt, Tasslimi, Bardi, Leader, & Hiatt, 2012). Pertussis is a highly contagious respiratory disease that can be spread by coughing. The cough can last for months and cause serious health problems. As of October 2012, Washington, DC and 48 other states have seen an increase in reported pertussis outbreaks compared to the same time in 2011. A provisional count indicated 4,000 cases of pertussis have been reported to the Centers for Disease Control and Prevention (CDC) and 16 deaths in 2012. The majority of deaths occurred in infants under 3 months of age, children between the ages of 7 and 10 years, and adolescents between the ages of 13 and 14 years (CDC, 2012b). According to the CDC, the tetanus, diphtheria, and pertussis (Tdap) vaccine is recommended for preteens between the ages of 10 and 12 years for protection against tetanus, diphtheria, and pertussis. Protection provided by the Tdap vaccine during childhood wanes and a booster Tdap shot are needed (CDC, 2012b). Receiving the booster not only protects preteens but also the people around them, especially infants and elders. When a majority of the community is immunized, the spread from person to person is less likely and is known as *herd immunity*. Newborns and people with chronic illnesses are offered some protection because the disease has less opportunity to spread.

This protection is important for infants not immunized, people immunocompromised, and people unable to receive vaccinations (Kennedy, Pruitt, Smith, & Garrell, 2011). There is a growing concern that as immunity wanes and others are not immunized there will be a considerable risk for outbreaks of pertussis.

There is no cure for pertussis; the best offense is to protect the community from contracting and spreading the disease by vaccination. Children receive five doses of DTaP vaccine before they turn the age of 7 years: one vaccine at 2, 4, 6 months, one vaccine at 15-18 months, and one vaccine between 4 and 6 years of age. Once children become 10 years of age they are eligible for the Tdap booster vaccine, which contains lower levels of diphtheria and pertussis to decrease reactogenicity. Known side effects to the vaccine are injection site redness, swelling, nausea, vomiting, diarrhea, headache, fatigue, and myalgia. Children can have a Tdap booster vaccine as early as 7 years if they missed one of their five doses before the age of 7 years. It is recommended that adults 18 years and older should substitute a Tdap booster vaccine in place of a tetanus and diphtheria (TD) vaccine. Most recently, the Tdap vaccine as a booster shot to prevent pertussis has been approved for adults over the age of 65 years (CDC, 2012c).

Problem Statement

Pertussis was declared an epidemic in Washington State in April 2012. The CDC reported 2,520 cases by June 16, 2012, a 1300% increase from the same time in 2011 (Debolt et al., 2012). The adult age group has been underdiagnosed with pertussis based on the fact that pertussis is under-recognized as a cough related issue (CDC, 2012c). The problem is preventing and controlling the spread of the disease to infants and others at greatest risk for severe disease because of waning immunity. The CDC has reported a

twofold to threefold increase in pertussis outbreaks in the state of Mississippi from 2011 to 2012 (CDC, 2012b).

Statement of Purpose

The purpose of the study was to identify if preteens between the ages of 10 and 12 years and adults 18 years and older are being adequately screened and given the pertussis booster vaccination Tdap to prevent the transmission of bacteria *Bordetella pertussis*. The researchers sought to discover if primary care providers are seeking pertussis immunization status and offering the patients the Tdap vaccine to prevent pertussis. Additionally, the researchers attempted to determine if educational material, such as the Vaccine Information Statement (VIS) for Tdap, was available for patients. Finally, researchers demonstrated the importance of recommending the Tdap vaccine to patients in targeted age groups.

Significance of Research Project

Parents miss an average of 44 days from work and experience a substantial economic burden because of the direct and indirect cost of pertussis. Children are seen in doctors' offices, emergency rooms, and hospitals with many missed days of school as a result of pertussis. The disease has the highest incidence of morbidity and mortality in infants because of decreased immunity from immature immune systems. Preventing the spread of disease in the infant age group by immunizing those individuals in close contact with the infant is considered cocooning.

Mothers are given the immunization during pregnancy or during the postpartum period to protect the infants; however, more efforts are needed to immunize the entire

household (Casler et al., 2012). The father, siblings, grandparents, and any immediate caregivers ideally should be vaccinated at least 2 weeks before contact with the infant. A missed opportunity to immunize on a day-to-day basis for adolescents and adults is a barrier which needs attention. A strong recommendation from a primary care provider has the most powerful influence on adults' decision to accept the vaccine. One way to become a more effective vaccinator is make an organizational change and have the office staff understand the importance of the immunization schedule. Every staff member needs to know the importance of immunizations; an assistant who answers the phone should not discourage patients from getting vaccines because of his or her own philosophy (Casler et al., 2012). Primary care providers have an increasingly difficult obstacle to overcome while trying to increase vaccination rates with adults. The lack of regular healthcare visits and lack of emphasis on documentations of adult immunizations are identified barriers that need to be addressed by the medical community (Casler et al., 2012).

Theoretical Foundation

Nola J. Pender's revised Health Promotion Model (HPM) was used for the framework of this study. Pender believes each person has a set of beliefs that can be inherited or acquired behavior. This behavior can result in the level of participation in self-health promoting behaviors. Actively endorsing immunization for patients is a means for the provider to increase the patient's commitment in health-promoting behaviors. A patient's experiences and beliefs can alter the perceptions of immunization to prevent pertussis. The researchers obtained vaccine information from select primary care offices in Mississippi. The goal was to identify if Tdap screening and immunizations were being provided to those in need of the vaccine.

Pender conducted research in 1978, in which she explored the behavioral characteristics of a community and the prediction of the community to use health promotion services when available if given by a nurse practitioner. More than 60% of people in the community would use the services if they were available. Using Pender's model in association with pertussis immunizations, a belief is formed in which health education of pertussis as a preventable disease through immunization would help the individual accept the vaccine based on his or her strong self-health promoting beliefs (Pender & Pender, 1980).

Research Questions

The following research questions were used for this study:

1. Are adults 18 years and older being screened and offered the Tdap booster vaccination?
2. Are preteens between the ages of 10 and 12 years being screened and offered the Tdap booster vaccine?
3. Do primary care offices have and distribute education material about the Tdap immunization?

Definitions of Terms

The following are definitions of terms used in the study:

Pertussis

Conceptual: Known as a highly communicable disease caused by the bacteria *Bordetella pertussis*, causes paroxysmal or spasmodic coughing that usually ends in a prolonged, high-pitched, crowing inspiration, also known as whooping cough (Porter & Kaplan, 2011).

Operational: A vaccine preventable cough-related infection, which is reemerging because of waning of the protection from childhood immunizations. The researchers are attempting to discover if the immunization for the infection is being giving to those who meet CDC age criteria.

Diphtheria-Tetanus-Pertussis (Tdap)

Conceptual: Diphtheria (D) vaccines contain toxoids prepared from *Corynebacterium diphtheria.* Tetanus (T) vaccines contain toxoids prepared from *Clostridium tetan*. Acellular (a) pertussis (P) vaccines contain semi-purified or purified components of *Bordetella pertussis.* There are two types given in the United States: DTaP given to children under the age of 7 years and Tdap for adolescents and adults. The Tdap contains lower doses of diphtheria and pertussis components (indicated by the lower case d and p) (Porter & Kaplan, 2011).

Operational: The first vaccine for preteens, adolescents, and adults over the age of 65 years, which protects against pertussis as well as tetanus and diphtheria given as a booster shot. The immunization being studied should be given in primary care clinics to prevent pertussis.

Preteen

Conceptual: A human 10 through 12 years of age (Porter &Kaplan, 2011).

Operational: The age group the CDC recommends receiving the first Tdap booster shot.

Adult

Conceptual: A human 18 years of age and older (Porter & Kaplan, 2011).

Operational: The age group the CDC recommends receiving a Tdap booster in place of a TD vaccine one time during adulthood.

Primary Care Providers

Conceptual: A healthcare professional who helps in identifying, preventing, and treating illness or disability (Porter & Kaplan, 2011).

Operational: A healthcare professional (e.g., doctor, nurse practitioner, or physician assistant) that would screen, administer, and chart Tdap immunizations.

Assumptions

The researchers assumed primary care providers know the correct immunization schedules and when to administer the correct vaccination. The researchers assumed that each chart has adequate documentation of Tdap vaccine.

Summary

Cyclic increases in pertussis happen approximately every 4 to 5 years, which sometimes reaches epidemic proportions similar to the amount of outbreaks the United States has experienced this last year. Pertussis is also being underdiagnosed because it is not looked at as a differential diagnosis for a cough-related disease in preteens and adolescents. Primary care providers need to explore different strategies to increase immunization throughout the age span, such as (a) decreasing missed opportunities during day-to-day patient care interactions, (b) developing a more comprehensive way to keep track of adolescent and adult vaccination, and (c) educate the office staff on importance of the immunization. Dr. Audrey Stevenson, who coordinates family health related services for the Salt Lake Valley Health Department, stated that, "We still have

much to do in order to educate and vaccinate. None of us is as good as all of us" (Casler et al., 2012, p. 6).

CHAPTER II

Review of Literature

The purpose of the study was to identify if preteens between the ages of 10 and 12 years and adults 18 years and older are being adequately screened for the pertussis booster vaccination to prevent the transmission of the bacteria *Bordetella pertussis.* *Bordetella pertussis* is a bacterium that causes pertussis, also known as whooping cough. Pertussis is a highly contagious respiratory disease that can be fatal in infants and the elderly. According to the (CDC, 2012b), 27,550 cases of pertussis were reported in the United States in 2010. However, many cases of pertussis may go undiagnosed and unreported. The 27,550 cases of pertussis in 2010 is the highest reporting of pertussis since 1959 with a reported 40,000 cases. The spread of pertussis is prevalent and increasing in the United States with an estimated 300,000 deaths occurring worldwide each year. Pertussis is preventable and remains one of the leading causes of vaccine preventable deaths. The most effective way to prevent pertussis is to vaccinate children with the Tdap vaccine (CDC, 2012b). Since protection from the vaccination will lose effectiveness over time, preteens, adolescents, and adults need a Tdap booster (CDC, 2012c).

Literature reviews were conducted to obtain information regarding the appropriate screening and administration of Tdap in adolescents and adults with the hope to prevent the spread of pertussis. The research studies suggested that initial prevention begins with primary care providers (PCP) who play a vital role in the effectiveness of screening and treatment against pertussis. The review of literature supported the recommended guidelines of the CDC for screening and booster vaccine of all preteens between the ages of 7 and 12 years and adults over 65 years. The six

literature reviews provided the results of additional studies strongly related to the current study. The reviews provided information regarding theory, diagnostic tests, knowledge gap in primary care, and recommendations concerning the Tdap vaccine.

Pender's theory is the framework used to guide the research on prevention of pertussis since the theory focuses on health promotion, illness prevention, and upholding well-being. Pender's Health Promotional Model theory has many key elements that address the influences of an individual's decision and behavior that lead to health-promoting actions. The most relevant part of the Health Promotional Model is the variable of interpersonal influences. Interpersonal influences are the person's thoughts or beliefs about the behaviors, attitudes, and beliefs of others and may not accurately reflect those behaviors, attitudes, or beliefs (Pender, Murdaugh, & Parsons, 2006). An individual may be influenced from a variety of sources, such as family, peers, and healthcare providers.

With the epidemic rise in the outbreak of pertussis, the responsibility of a healthcare provider is to be the main source of influence for the community and promote participation in prevention of further spread of the disease. The healthcare provider may use an array of various methods to encourage individuals to participate in the prevention of pertussis. The healthcare provider should participate in the necessary steps of screening, educating, and encouraging immunization within the community. Increasing an individual's knowledge, awareness, and detection of pertussis will allow a decrease in the spread of pertussis in communities and newborns—currently the population at highest risk for mortality with pertussis. Positively influencing a person's decision-making and actions could be as simple as providing accurate and educational information. When accurate information is provided, individuals can take part in their own care in prevention

of diseases and illnesses. Applying the Health Promotional Model will provide guidance in creating a supportive and high quality implementation plan, which leads to achievement of health-promoting behaviors.

Review of Related Research: Diagnostic Test for Pertussis

Hajia, Rahbar, Fallah, and Safadel (2012) revealed a diagnostic tool referred to as the PRC, which is a tool that accurately assists in screening for pertussis in individuals who may be difficult to diagnose. Hajia et al. (2012) conducted a quantitative research study. Using a systematic approach, the authors collected data with a numerical statistic technique to reflect the results of each participant's positive and negative test outcomes. Early signs and symptoms of pertussis are often nonspecific and difficult to determine in the early stages. Undiagnosed patients infected with pertussis have a high risk of transmitting the disease to others in the community (Hajia et al., 2012). The authors sought to discover a way to help improve laboratory diagnosis tests for pertussis and to distinguish which test is more sensitive and specific for detection of pertussis. The main diagnosis test researchers wanted to study was on Polymerase Chain Reaction (PCR). PCR is a molecular technique used to detect DNA sequences of the *Bordetella pertussis* bacterium and, unlike culture, does not require live bacteria present in the specimen (CDC, 2012a).

Hajia et al. (2012) did not state a specific research question. To evaluate the frequency of *Bordetella pertussis* among received specimens, the authors stated the concern and necessary reasons for the conduction of research. The authors' purpose was to investigate several laboratory diagnostic tests that would prove to be more sensitive in diagnosing pertussis.

A cross-sectional study was the method used to conduct the research. A cross-sectional study was appropriate for this type of study—observing the chosen population at a point in time. This type of study allows the authors to describe the prevalence of the pertussis and help validate the reliability of the test. The design method tested 93 males and 45 females for a total of 138 participants. All of the participants were under 6 months of age and suspected of having whooping cough. The researchers used special swabs to collect specimen from the sample. The specimen was used in two tests—the ELISA and the Polymerase Chain Reaction. The tests, which resulted positive for *Bordetella pertussis,* were recorded in SPSS software and converted into percentage. The population in the study was children < 6 months old suspected of whooping cough. The participants' vaccination history was used to define the sample selection. Subjects were excluded if they have been vaccinated for pertussis.

Data were collected using the diagnostic tests ELISA and PCR. In ELISA, a kit was used to detect *Bordetella* antigen containing pertussis toxin by applying enzyme linked immunosorbent assays to the commercial kit (Hajia et al., 2012). In PCR, a High Pure PCR Template preparation kit was used to perform DNA extraction to detect specific genome in the patients with pertussis (Hajia et al., 2012). The data were calculated by software called SPSS, which converted the results into a percentage. The data established how sensitive each test was to detect *Bordetella pertussis* in the population. The sample for the research was a nonrandom sample of the population. The sample that the researchers chose to conduct the study was on 6-month-olds suspected of having whooping cough and unvaccinated infants.

The statistical method used to analyze the data was a specific type of software, SPSS software version 16. The SPSS software is a complex data collection analysis

procedure. A limitation of Hajia et al. (2012) was that the research did not thoroughly explain the method of data collection. The graph showed negative and positive controls of each participant; however, it did not explain specific reaction versus internal control. Hajia et al. also failed to explain the background sample or result. The findings concluded that the PCR method is verified to be sufficient, stable, and able to provide reproducibility of results when tested. The test reported a high sensitivity ratio. Hajia et al. (2012) stated that the testing for pertussis by PCR method is highly sensitive but recommended adding the ELISA testing to help eliminate any false positive with either test.

In conclusion, Hajia et al. (2012) could have added more diverse participants to the study so the outcome of the findings could have been compared between two different populations to strengthen their study. Strengths of Hajia et al.'s study provided the nurse practitioner student with a better understanding regarding the various tests used to detect *Bordetella pertussis*. The research by Hajia et al. was very informative regarding the detailed steps of ELISA and PCR testing. Prior to the vaccination, the public was not aware of the infection. The study was conducted in Iran, which shows that pertussis is not only a problem in the United States. It is possible that in the near future that the U.S. along with other countries may be battling the spread of pertussis resulting in an epidemic problem. Knowing the significance of the problem will increase the eagerness of the public, healthcare providers, and researchers to strive to find a solution for the prevention against pertussis.

Hajia et al. (2012) was valuable to the current research study as it emphasized the importance of appropriate screening to prevent pertussis. Diagnosing pertussis may be delayed in non-symptomatic patients or patients who do not present with the classic

symptoms of pertussis. The delay in diagnosing will cause an increase in transmission of the infection in the community. It is important to note that screening for the infection should not only be based on clinical signs and symptoms. Hajia et al. (2012) proved a positive outcome when utilizing PCR in screening for pertussis. Therefore, it was used in the current research project to facilitate the screening process for pertussis and support the diagnosis.

Knowledge Gaps in Primary Care

Gannon, Qaseem, Snooks, and Snow (2012) exposed the necessity of primary care providers (PCP) focusing on preventable healthcare needs at each visit. Increasing the knowledge base for PCPs will encourage them to recommend the booster vaccine to protect against pertussis. The purpose of Gannon et al.'s (2012) study was to improve the immunization practices in primary care settings using a team approach. Their study was a quantitative prospective study. The quality of care in the primary care setting lacked preventive care because the physician and office staff were focused on acute needs of the patients. The lack of quality in our nation's healthcare system has increased because our focus is on complex medical problems. The American College of Physicians (ACP) developed a quality improvement curriculum to encourage physicians and practice teams to learn about the current recommendations and practices for adult immunization. Childhood vaccinations have become a public health success and adult vaccination rates are not increasing, thereby prompting a change toward lifespan immunizations. Adults are the primary source of infectious transmission to unprotected infants (Texas Department of State Health Services, 2012).

The authors evaluated the development of quality improvement teams in the primary care setting that will have an impact on adult immunization rates. The team

approach was developed and taught by two main faculty researchers to 20 primary care practices. Teams of four (a physician, nurse, front office staff, and a medical tech) were frequent combinations. The researchers used quality improvement methods to teach a team approach, thereby increasing knowledge, education, and administration of vaccines to adults.

"The null hypothesis for this study was that the intervention would have no impact on the immunization rates of the practice after the intervention" (Gannon et al., 2012). Seventeen of the 20 enrolled practices completed the study. The sample included the practice of randomly auditing 35 charts at two points in time—baseline and 12 months later. The population included patients 18 years and older and those who had been under the clinic's care for more than one year. Data were collected for influenza, pneumococcal, tetanus diphtheria (Td)/Tetanus diphtheria pertussis (Tdap), hepatitis A, hepatitis B, meningococcal, varicella, herpes zoster, and human papilloma virus. During the two specific dates, the quality improvement teams were given access to online educational tools, feedback surveys, and conference calls coaching quality improvement. Patient chart abstraction data were collected twice during the study from two different sources. First, a physician practice pattern survey was used and secondly a patient chart abstraction form. The physician practice survey used a Likert-scale response and captured the beliefs of the physician practice using a team approach for the vaccination of adults in their practice.

Patients' right protection was not mentioned. Gannon et al. (2012) did not avoid bias in sampling. Several biases were cited and considered limitations for the study. The statistical data methods were chi-square tests and analysis of variance tests. The p values of $\leq .05$ were considered statistically significant. The Td/Tdap rates went from 45.6%

pre-intervention to 55% post-intervention ($p \leq .01$). Physicians made significant improvements with their immunization rates by discussing immunization with their patients and giving the immunizations themselves. The physicians also saw significant improvement by using the CDC immunization schedule. The practice teams were taught small steps and changes that would increase their success at sustained change.

Gannon et al. (2012) recommended the information could encourage small clinics with paper-based practices to use this information and change their practices with minimal effort. The program encouraged the support team to give a small part of their autonomy to better serve the goals of the practice. The change in adult vaccination takes a team approach, which is invested in quality improvement.

The current study specifically addressed whether adults and preteens between the ages of 11 and 12 years are being screened and given the Tdap vaccine in select practices in Mississippi. Gannon et al. (2012) estimated that 50,000 to 70,000 U.S. adults die each year from diseases that could be prevented by vaccination. However, quality gaps in healthcare and missed opportunities for screening for appropriate vaccination exist between those recommended to receive vaccination and those who received the vaccination (Gannon et al., 2012). Researchers try to improve adult immunizations with a quality care-based intervention, which focuses on a team approach in the primary care settings. The team-based approach worked well in this study; it can be generalized that the same approach would work well in Mississippi. Improving adult immunization will decrease the rate disease is spread in the United States, including Mississippi.

Rossi-Foukes et al. (2010) disclosed that primary care providers' lack of knowledge has a huge impact on the prevention of pertussis. Rossi-Foukes et al. (2010) conducted a quantitative study using a methodical approach to collect data. Using a

numerical statistic structure for the collected data, the authors reflected accurately each participant's outcome to the research conducted. According to Rossi-Foukes et al, pertussis is underreported in the adolescent and adult populations with estimates as high as 1,000,000 cases among people aged 15-64 years annually in the United States. The researchers were completely aware of the existing studies documenting the underreported diagnosis of pertussis in adolescent and adult populations; however, the researchers did not identify documentations regarding physicians' knowledge of pertussis. Rossi-Foukes et al. (2010) were eager to conduct research to discover if the treatment of pertussis was dependent on the physician's knowledge concerning the highly communicable infectious disease.

Rossi-Foukes et al. (2010)'s questions and hypothesis were clearly stated and their desire to conduct the research was evident. The researchers questioned if a physician's lack of knowledge of pertussis is the likely cause of ineffectively diagnosing and treating pertussis. The hypothesis was that there are significant gaps in knowledge regarding pertussis, particularly among non-pediatricians. Rossi-Foukes et al. believed that Board preparation materials were not sufficient to educate physicians about pertussis (2010).

The independent sample *t* test and Mann-Whitney U test were the methods used to conduct the research on the physicians. The independent sample *t* test was used to compare the differences between pediatricians and non-pediatricians to determine if a significant difference in scores existed between the two groups. The scores were calculated by the percentage of correct answers based on a 12-question knowledge survey consisting of assessing the knowledge of pertussis in regard to the vaccines' immunity, transmission, reservoir, vaccination, treatment, diagnosis, and reporting requirements

(Rossi-Foukes et al., 2010). Upon completion of the independent *t* test, the Mann-Whitney U test was used to meticulously compare the individual questions and subject performance between pediatricians and non-pediatricians (Rossi-Foukes et al., 2010).

Rossi-Foukes et al. (2010) surveyed two neighboring counties in northern Illinois within two time periods. The first study was conducted from July 2002 through February 2003 in McHenry County, Illinois, based on a population of 296,389 residents. The second study was conducted from July 2003 through February 2004 in Kane County, Illinois, based on a population of 472, 482 residents. The samples were randomly selected to avoid bias. The criteria for selection required that the physicians be practicing and involved in patient care at least 20% of their time within the past year (Rossi-Foukes et al., 2010). The physicians were sampled as two groups, pediatricians and non-pediatricians. The non-pediatricians group included a wide variety of internists, family, and emergency physicians.

Rossi-Foukes et al. (2010) avoided bias sampling by using a list of physicians for each county provided by the local health departments. Within the provided list for Kane and McHenry counties, physicians were randomly selected. A total of 39 pediatricians, 65 internists, 58 family medicine physicians, and 2 emergency medicine physicians were selected to participate in the survey. A total of 167 physicians were selected to participate in the survey which consisted of 39 pediatricians, 65 internists, 58 family medicine physicians, and 12 emergency physicians. Of the 167 physicians, only 33 pediatricians, 31 internists, 32 family medicine, and 5 emergency physicians participated. A survey was sent to each participating physician via phone, mail, or fax. The accepted answers from the survey were measured as an average based on how the participants performed individually and as a group of either pediatrician or non-pediatrician.

Data from the survey were separated into two groups: pediatrician and non-pediatrician. The answers from the two groups were analyzed and reviewed based on knowledge and correctness on each subject of the survey. An average was used for each topic. The results revealed that overall pediatricians scored higher than non-pediatricians. The pediatricians also answered more accurately on 9 of the 12 knowledge questions except questions regarding reporting, transmission, and treatment (Rossi-Foukes et al., 2010). Fifty-two physicians suspected pertussis on the survey; however, only 12 physicians reported the diagnosis to the health department. Many of the physicians who did not report the cases stated it was because of lack of positive laboratory confirmation. Researchers discovered that family practitioners were less likely than pediatricians to test for pertussis and less likely to diagnosis a patient with pertussis when presented with the standardized symptoms (Rossi-Foukes et al., 2010).

Rossi-Foukes et al. (2010) believed that the knowledge deficit among non-pediatrician on the awareness of pertussis derived early in medical training based on inadequate coverage of pertussis in medical school and residency curricula. Rossi-Foukes et al. recommended a more comprehensive coverage of pertussis in early medical training along with a pediatric board preparation tool similar to those currently used by pediatricians.

A limitation of Rossi-Foukes et al.'s (2010) study was that it did not cover precisely the format of the survey and the scale used to evaluate the answers. Rossi-Foukes et al. provided valuable information to help prevent the spread of pertussis and concluded that prevention of the spread needs to be targeted on accurate diagnosis and reporting from the physician's standpoint.

Rossi-Foukes et al. (2010) was useful in the current research project to determine if healthcare providers are knowledgeable about proper screening and administration of the Tdap vaccine. A healthcare provider's role has a big impact on the awareness and detention of pertussis in adults and adolescents. Rossi-Foukes et al. highlighted a lack of knowledge among healthcare providers which leads to interference with reducing pertussis transmission in the community. A more effective method of prevention and treatment of pertussis will occur if the knowledge gaps are restored. Rossi-Foukes et al. (2010) provided baseline data quantifying pertussis knowledge among healthcare providers.

Recommendations for Tdap Vaccine

Based on a review of the literature, recommendations for the Tdap vaccine are as follows:

The Advisory Committee on Immunization Practices (2006) examined the safety and effectiveness of the Tdap vaccine among preteen and adolescent age groups. Pertussis is a highly contagious infection affecting infants, preteens, adolescents, and adults. The tetanus toxoid, reduced diphtheria toxoid, and an acellular pertussis (Tdap) vaccine have been recommended by the Advisory Committee on Immunization (ACIP) (2006) and the (CDC, 2012b) as a way to protect adolescents and adults from acquiring and spreading the disease. In addition to pertussis, adolescents who live in crowded living conditions similar to college dorms are also at risk for acquiring N. Meningitis infection, which can cause meningitis. The tetravalent meningococcal polysaccharide protein conjugate (MCV4) vaccine has been shown to protect against meningitis. The Tdap vaccine was mandated for children entering the sixth grade in New York, but the MCV4 vaccine was an optional immunization.

A quantitative prospective cohort study was performed. The purpose of the study was to evaluate changes in Tdap and MCV4 coverage following the New York State requirement that a Tdap vaccine be given before entering the sixth grade. The data were collected using a hospital-based immunization registry measuring Tdap and MCV4 coverage among adolescents between the ages of 12 and 14 years in New York City at three time points: pre-mandate, mandate year plus one, and mandate year two.

The research questions for the study were as follows: Will a new mandate for the Tdap vaccine being given to sixth graders improve the Tdap vaccine coverage for sixth graders and for non-mandated age groups? Will the Tdap vaccine mandate increase non-mandated, age-appropriate vaccines?

Data were gathered over three distinct periods of time: (a) October 1, 2006–time pre-mandate, (b) October 1, 2007–the year of the mandate, (c) October 1, 2008–one year after mandate. EzVac, a web-based registry that consolidates immunization records for all clinics and hospitals apart of the New York-Presbyterian (NYP) hospital system, was used to collect data (ACIP, 2006).

Among the patients who were Tdap eligible, the Tdap vaccine coverage increased from 29% premandate to 58% in mandate year one and 83% mandate year two for all age groups. The most notable increase was in age groups 11 and 12, but 13 and 14 increased in an acceptable percentage. The immunization coverage for the MVC4 increased in all age groups: premandate rates, 10%; mandate year one, 30%; and mandate year two, 60%.

The effectiveness of a mandate to increase coverage of a vaccine was substantial, which is consistent with previous studies. In addition, coverage among other age groups not targeted increased. The goals in increasing immunization to reduce pertussis transmission were laudable, but reliance on school mandates is a cause for concern. The

mandates put stress on already overburdened school systems, and mandates can cause parents to experience distrust. The MCV4 non-mandated vaccine administration rates increased, and teaching provider to screen for all vaccines instead of just-mandated vaccines most likely attributed to this increase.

Weston, Friedland, Wu, and Howe (2011) examined the safety and effectiveness of the Tdap vaccine among the elderly. Weston et al. (2011) conducted a quantitative study. The authors identified variables and collected data in a numeric form. Research has validated that immunity against pertussis diminishes as an adult ages despite receiving a TDAP vaccination as an infant. In 2005, the CDC (2005) recommended individuals between the ages of 11 and 65 years should receive a booster vaccination to prevent pertussis. The (CDC, 2012c) also advised adults < 64 years old to receive a booster vaccination for pertussis if close contact to infants < 2 months of age is frequent (Weston et al., 2011). However, the Tdap vaccination for adults > 65 was not recommended due to the lack of safety and immunogenicity data of Tdap use in this age group (Weston et al., 2011). Weston et al. sought to discover the safety and immunogenicity data for adults < 65 receiving the Tdap vaccination. Weston et al. also wanted to identify if there really are risks for adults > 65 years.

Weston et al. (2011) found further research in 2008 revealed that the high incidence of pertussis significantly increased in adults > 65 years. The researchers clearly stated that adults > 65 years should receive the Tdap vaccination. Weston et al. declared that vaccinations provided two valuable benefits. Two of the benefits included prevention of an individual from contracting the disease and prevention of the infected individuals from exposing the disease to other high-risk candidates such as infants.

Weston et al. (2011) conducted two studies to test the safety and immunogenicity of Tdap. In Study A, subjects received a single dose of Tdap along with a flu vaccine either administered at the same time or given one month apart (Weston et al., 2011). In Study B, participants received either the Tdap or Td vaccine. To ensure accuracy of results, antibodies were measured precisely prior to vaccination and one month post-vaccination.

To protect the rights of each individual, a signed written consent was required prior to the study. The subjects' rights were protected by the principles of Good Clinical Practice and the Declaration Helsinki. The study consisted of data collection over two separate time periods. Study A was conducted in 12 centers in the United States between October 2006 and February 2007. Study B was conducted in 24 centers in the United States between February 2009 and October 2009. To participate in the study, the subjects had not received the Td booster within the last 5 years, had a history of diphtheria, tetanus or pertussis disease, and had not received an influenza vaccine within 6 months of the study (Weston et al., 2011). The qualified subjects were then placed into two groups for Study A and Study B. A total of 217 subjects received the Tdap vaccination along with the flu vaccination in Study A, and 887 subjects received either the Tdap or Td vaccination in Study B. A total of 1,104 subjects participated in the two studies.

Blood samples were taken from each subject prior to initial vaccination and one month after each subject received vaccination. The vaccine was administered intramuscularly into the deltoid in the non-dominant arm. For Study A, researchers used the enzyme linked immunosorbent assays to measure antibodies against D, T, and pertussis antigens. A booster response was defined as a post-vaccination antibody concentration of $\geq$ 20 El/ml in initially seronegative adults and an increase in the post-

vaccination concentration of ≥ 4 times the pre-vaccination antibody concentration in subjects with pre-vaccination antibody concentrations between 5.0 El/ml and > 20El/ml (Weston et al., 2011). In Study B, the subjects were instructed to document any adverse side effects experienced after receiving the vaccination during the 4-day follow-up period on a diary card. For Study A, the follow-up period for solicited adverse events was 15 (Weston et al., 2011). Subjects were to document any experience of local and general adverse effects. Local adverse effects included pain, redness, and swelling at the injection site. General adverse effects included fever, fatigue, gastrointestinal symptoms, pain, muscle pain, shivering, and headache (Weston et al., 2011). The researchers used a scale of 0-3 to grade each adverse effect experienced by the participants.

The researchers analyzed their data with a statistical analysis computing an average. In Study A, computer software SAS and Proc Statx act 5.0 were used. In Study B, Drug Development version 3.5 and Statxact-8 procedure were used to obtain statistical analysis results. The analysis of safety was performed on the total vaccinated cohorts, which included all subjects who had received at least one vaccine dose (Weston et al., 2011). The subjects were grouped according to the vaccine received for the analysis. Study A concluded a difference in immune response to Tdap or influenza vaccine observed between co administered or sequentially administered vaccines did not exist (Weston et al., 2011). Study B showed adverse reaction ranging from generally mild to moderate in intensity (Weston et al., 2011). Based on results of the study, it is safe to administer the Tdap vaccine with or without the influenza vaccine to adults ≥ 65 years. The study also showed when the Tdap is administered to adults 65 years or older there is immunogenicity present where the adult could provoke an immune response to protect against pertussis. Weston et al. (2011) recommended providing pertussis vaccination to

adults > 65 years. The elders have been associated as transmitters of pertussis disease to young infants and children. Administering vaccination to elders would help prevent pertussis-associated morbidity in the elderly population and decrease transmitting of pertussis to vulnerable infants and young children (Weston et al., 2011). Weston et al.'s study cited two distinctive studies confirming the safety of vaccination and acknowledgement of an affirmative change in the body when vaccinating adults > 65 years.

The current research study addressed whether or not adolescents and adults are being screened and administered the Tdap vaccine. Weston et al. (2011) was useful to the current study because it provided knowledgeable information about the safety and importance of Tdap immunization in adults > 65 years. The incidence of pertussis in the United States has increased yearly, with the greatest rate of increase observed in adults ≥ 65 years (Weston et al., 2011). Weston et al. concluded that increasing age does not provide immunity against disease; hence, immunization is essential. Based on the results of Weston et al., the current researchers included adolescents and adults which allowed proper screening throughout the age span.

Carstensen et al. (2012) examined the safety and reaction of the Tdap vaccine administered to healthy adults. The purpose of Carstensen et al. (2012) was to obtain clinical documentation of the safety and immunogenicity of the Tdap vaccine when given to healthy adults. Carstensen et al.'s study was a double-blind, non-inferiority clinical trial. The relevance increased the knowledge base for PCPs and encouraged them to recommend the vaccine as a booster to protect against whooping cough (Carstensen et al., 2012).

Pertussis remains one the leading causes of vaccine preventable deaths with an estimated 300,000 deaths occurring worldwide every year. The ACIP recommends that all adults > 18 years receive a Tdap vaccine as a booster in lieu of the Td vaccine to protect against pertussis. The recommendation has indicated the relevance of the safety of the Tdap versus the Td (Carstensen et al., 2012).

Several questions related to Carstensen et al.'s study were answered after the complete population was immunized with one of the two vaccines. Vaccination reactions were first studied. For the first 72 hours, did the patient have any injection site pain, swelling, or erythema? Did the patients have any headaches, fatigue, or myalgia? After, 28-35 days, did the seroprotection rates increase in both Tdap and Td for tetanus and diphtheria and was the seroprotection increased for pertussis in the Tdap sample (Carstensen et al., 2012)

The method of a double-blind, randomized, controlled trial was used for the study. The patients' blood samples were drawn before the immunizations were given and one month after the immunizations for serological analysis and adverse events were recorded during the month after injections were received. Prior to initiation of the trial, researchers went before their ethics committee and approval was obtained per protocol. The trial was conducted in accordance with the Declaration of Helsinki 59th WMA General Assembly in Seoul and was registered per protocol under clinical trials (Carstensen et al., 2012).

The data were gathered at initiation of the trial and one month later. The target population consisted of 800 healthy female and male adults over the age of 18 years who had completed primary vaccination with Tdap in Denmark. Vaccinations were confirmed per vaccination card. In addition to the protocol, the trial required that at least 25% of

subjects be over the age of 30 years and 10% be over the age of 40 years. The main bias or exclusions criteria were subjects with immune deficiency, progressive neurological disease, uncontrolled epilepsy, and progressive encephalopathy. The data were collected at two trial visits. First, a pre-vaccination blood sample was drawn and the subjects were vaccinated with either Tdap or Td. Secondly, 28-35 days later a post-vaccination blood sample was drawn, and adverse events and concomitant medications were recorded. It was impossible to identify which vaccine was given to each patient (Carstensen et al., 2012).

The statistical methods were computed via the SAS POWER procedure (SAS/STAT9.2), and a Wilson method was used without a continuity correction. The Tdap vaccine was found to be safe immunogenically and non-inferior to the Td vaccine when given as a booster vaccination to adults. The safety and immunogenicity of the Tdap vaccine had already been established in children and adolescent populations. Carstensen et al.'s (2012) study supports vaccination in the adult population.

The implications of Carstensen et al.'s study can be helpful to direct the focus of the current study. Focus of the current study was to determine if adolescents between the ages of 10 and 11 years and adults over the age of 18 years are being screened and offered the Tdap vaccination as a booster immunization. Knowledge of the immunogenicity and adverse reactions of the Tdap compared to the Td vaccine will provide information needed by PCPs who are still only giving Td vaccines. PCPs need to give Tdap vaccines in order to increase herd immunity of the pertussis disease.

Summary

The six literature reviews, along with Pender's theory of Health Promotion Model, provided valuable information and framework for the importance of the current

study. The literature review provided results of other studies that are strongly related to the current study. The reviews provided information regarding diagnostic tests, knowledge gap in primary care, and recommendations concerning the Tdap vaccine. The literature reviews increased the current researchers' knowledge base concerning pertussis and assisted in accurately collecting data for the study.

CHAPTER III

Methodology

A quantitative chart review was conducted to evaluate if healthcare providers are screening, recommending, and administering the Tdap vaccine to eligible patients, particularly preteens between the ages of 10 and 12 years and adults 18 years and older. A quantitative, retrospective chart review was used to review 200 charts from four different clinics. This chapter identifies the setting, sample, implementation, and data analysis used for the study.

Setting for the Research Study

The setting for the research study was four primary care clinics: 2 specialized in pediatric patients for ages 10 to 12 years and 2 internal medicine clinics for patients 18 years and older. Each of the four clinics in different regions of Mississippi provides a diversity of results. A pediatric clinic and internal medicine clinic from southwest Mississippi and a pediatric and internal medicine clinic from northwest Mississippi were sites used.

Sample

The population for this research study included patients receiving care at the pediatric and internal medicine clinics from January 2013 to March 2013. From each clinic, 50 charts were randomly selected for a total of 200 charts. The chart chosen had to fit in a set criterion. The criteria consisted of males and females between the ages of 10 and 12 years and 18 years and older who visited the clinic for any reason. The criterion for this research study was based on the recommendations of Tdap vaccination from the CDC in regard to children ages 7 through 12 years and certain adults ages 18 years and older.

Implementation of the Project

Approval to conduct the study was obtained from Mississippi University for Women Graduate Program and IRB (see Appendix A). Research data were gathered using two clinical sites in southwest Mississippi and two clinical sites in northeast Mississippi. Written consent was obtained from each participating clinic (see Appendix B). Each researcher selected 50 charts from each site, and both researchers collected 50 charts with dates of birth between 2001 and 2003 and 50 charts with dates of birth pre-1995. This retrospective chart review followed HIPPA guidelines, did not use any human participants, and maintained confidentiality at all times to protect information gathered. Researchers collected data using a researcher-designed data collection tool (see Appendix C). Questions for the tool were identified by review of literature based on CDC guidelines for the Tdap vaccine. Numbers were used to prevent a break in confidentiality. Collected data were stored onto a portable disc drive, which only the researchers had access. The drive was kept secure and locked throughout the project. After research was completed, all stored data were destroyed. The researchers examined each chart to evaluate whether or not screening and administration of the Tdap vaccine had been administered. The data established if primary care providers were screening, recommending, and administering the Tdap vaccination.

Data Analysis

In the current research project, descriptive statistics were used to collect data. The data were analyzed using medians, means, modes, and percentiles. A *t* test was used to compare results from each clinic to see if there were any significant differences.

Summary

The researchers utilized a retrospective, quantitative chart review. Each researcher collected data from 100 charts in the targeted age groups, 50 pediatric charts and 50 internal medicine charts. Based on data collected, the researchers could determine the consistency of screening and administering the Tdap vaccine at four different clinical sites in Mississippi. In addition, availability of Tdap vaccine education sheets were assessed at all sites to determine if the education sheets increased the vaccine rate.

CHAPTER IV

Presentation of the Findings

The purpose of this study was to evaluate primary care providers' attention in screening patients for pertussis in certain high-risk age groups. The researchers also evaluated whether Tdap was administered appropriately to those individuals to prevent the spread of an outbreak. The researchers reviewed the charts of patients who were between the ages of 10 and 12 years and 18 years and older. This chapter presents a description of the researchers' sample of study, demographics, and analysis of the data collected.

Description of the Sample

Demographics that were examined in the study included gender and certain age groups. A total of 200 charts were reviewed. Gender was almost exactly the same (see Figure 1). Of the 200 subjects, the majority were between the ages of 10 and 12 and 18 to 91 years old. In the adult age group, 53% (n = 100) represented the total participants that were screened and 47% were not screened. Out of 100 adult participants, 21% were given the Tdap booster vaccine, and 79% were not given the vaccine. In the pediatric age group, 78% (n = 100) represented the total participants that were screened and 22% of total pediatric participants who were not screened. Out of the 100 pediatric participants, 64% were given the Tdap vaccine and 36% were not given the vaccine.

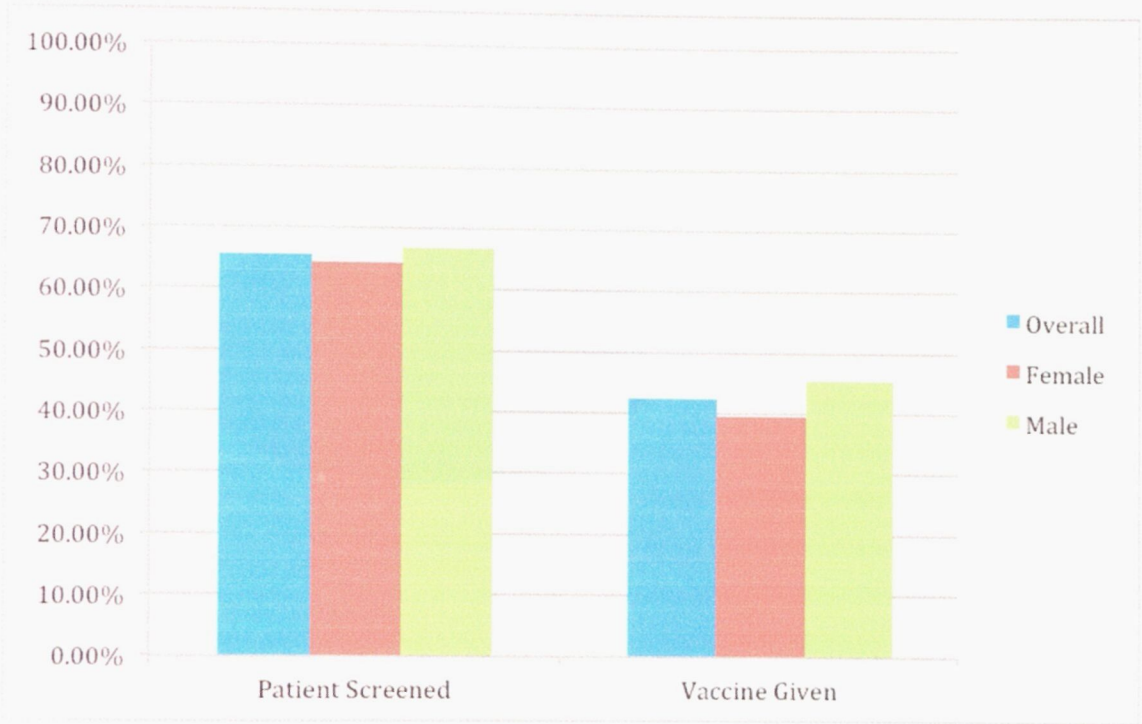

Figure 1: Representation of gender related to study sample ($N = 200$).

Research Questions

Research question 1. Are adults 18 years and older being screened and offered the Tdap booster vaccination? According to the data analysis, 53.00% of adult patients are being screened, and 21.00% of adult patients are being given the Tdap booster vaccine (see Figures 2 and 3).

Research question 2. Are preteens between the ages of 10 and 12 years being screened and offered the Tdap booster vaccine? The results of the study revealed that 78% of pediatric patients are being screened, and 64% of pediatric patients are being given the Tdap booster vaccine (see Figures 4 and 5).

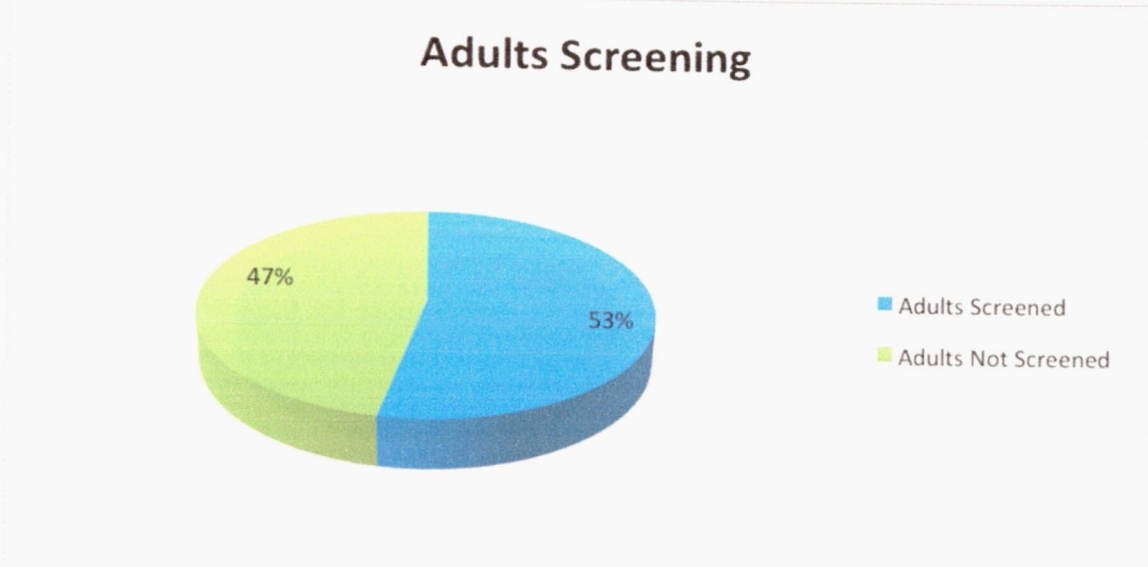

Figure 2: Representation of adult patients screened or not screened for Tdap vaccine (n = 100).

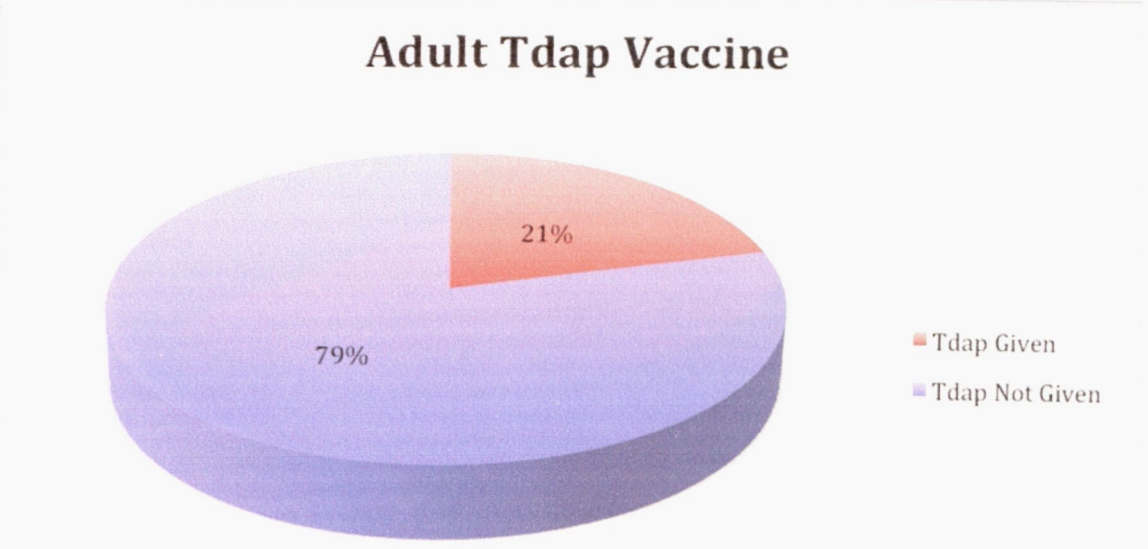

Figure 3: Representation of adult patients given Tdap vaccine (n = 100).

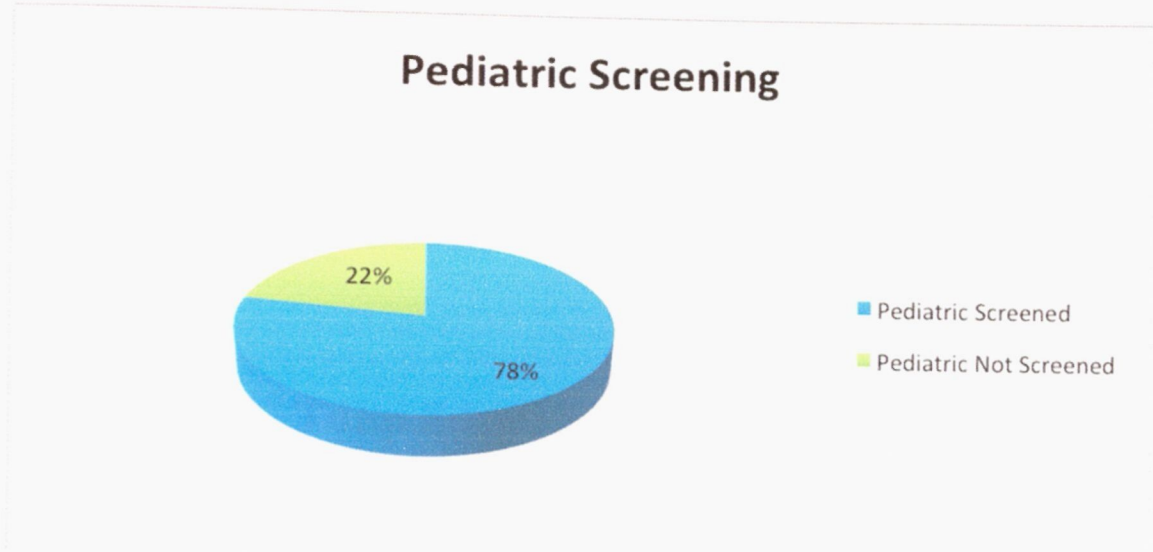

Figure 4: Representation of pediatric patients screened or not screened for Tdap vaccine ($n = 100$).

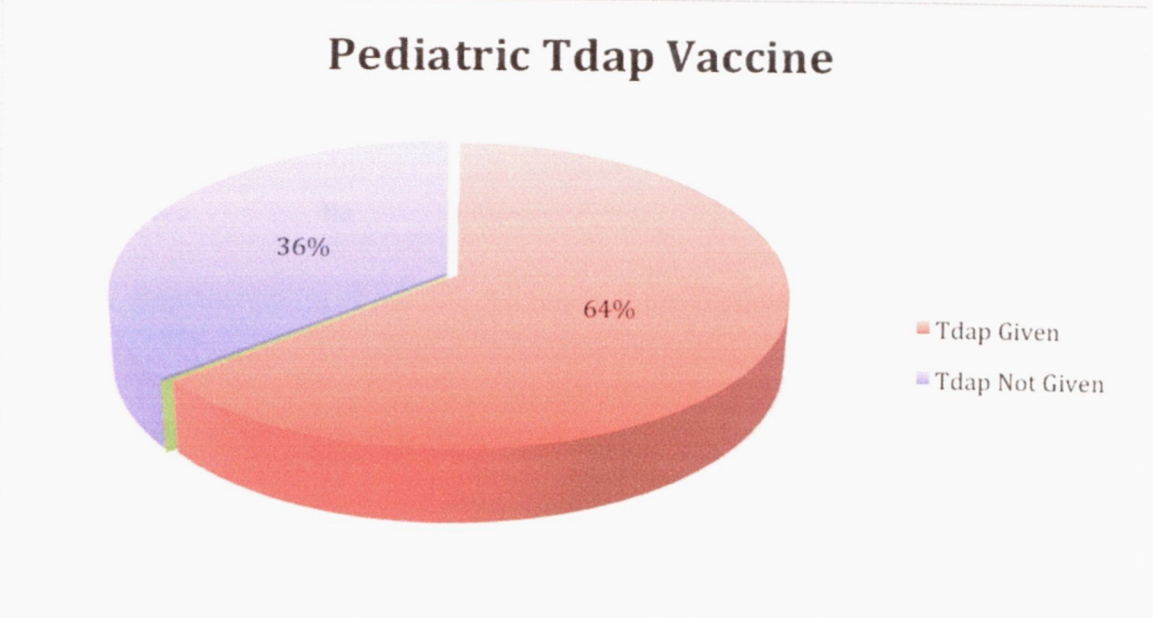

Figure 5: Representation of pediatric patients given the Tdap vaccine ($n = 100$).

Research question 3. Do primary care offices have and distribute education material about the Tdap immunization? Of the four offices where the populations were

studied, 100% ($N = 200$) of the offices had educational material about the Tdap immunization (see Figure 6). The occurrences of the educational material given out were statistically significantly higher for participants who had received a Tdap vaccination when compared to those who had not received a Tdap vaccination.

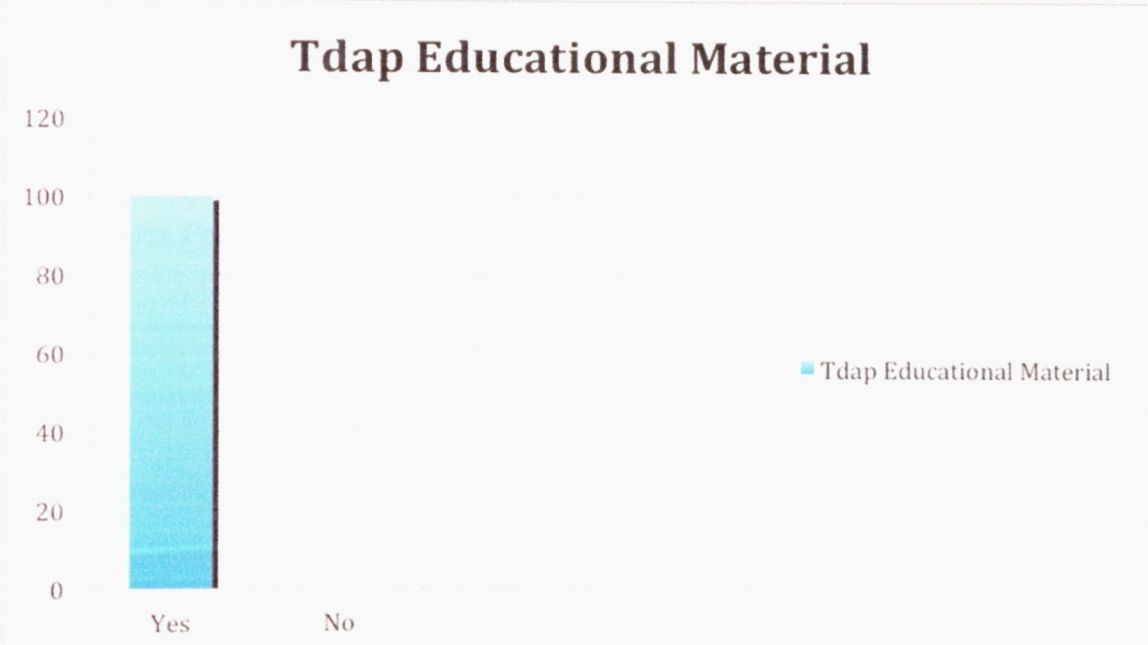

Figure 6. Representation of educational material for Tdap vaccination in the clinics ($N = 200$).

Additional Findings

It should be noted that the differences in screening occurrence rates are statistically significantly different between age groups, $\chi^2(1, 200) = 13.829, p < .001$, with pediatric patients being screened more than adult patients. The differences in vaccine delivery rates were also statistically significantly different between age groups, $\chi^2(1, 200) = 37.831, p < .001$, with pediatric patients being given the Tdap booster vaccine more often than adult patients.

There was no significant difference in screening rates, $\chi^2(1, 200) = 0.118$, $p = .731$, or vaccination administration rates, $\chi^2(1, 200) = 0.700$, $p = .403$, based on patient gender. There were also significant differences in the data based on which location the researcher's analyst collected the data. Patients evaluated in the northeast Mississippi had a significantly higher rate of screening, $\chi^2(1, 200) = 24.096$, $p < .001$, and a significantly lower rate of vaccination, $\chi^2(1, 200) = 3.458$, $p = .063$, compared to the patients evaluated in south Mississippi (see Table 1).

Table 1

Screening for Pertussis and Tdap Vaccine Given Based on Gender, Age, and Location (N = 200)

		%	
	n	Patient screened	Vaccine given
Patient type			
Adult	100	53.00	21,00
Pediatric	100	78.00	64.00
Gender			
Female	100	64.36	39.60
Male	100	66.67	45.45
Researcher's analyst			
Northern	100	82.00	36.00
Southern	100	49.00	49.00

Summary

In the retrospective chart review, the researchers attempted to identify whether primary care providers were screening patients to prevent further outbreak of pertussis. A review of 200 charts was performed and the data were analyzed. Data were first compiled in Microsoft Excel. Data were collected from 200 clients (100 male and 100 female). Adult patients ranged in age from 19 to 91 years ($M = 55.07$, $SD = 16.61$). Pediatric patients ranged in age from ranging in age from 10 to 12 years ($M = 10.97$, $SD = 0.81$). Subsequent analyses were performed using Minitab statistical software, version 16. Of the subjects studied, overall 65.50 % of patients were screened and 42.50% were given the Tdap booster.

CHAPTER V

The Outcomes

The purpose of this research project was to determine if healthcare providers in Mississippi were screening and administering the Tdap to appropriate patients. Pertussis was declared an epidemic in Washington State in April 2012. According to the CDC, 2,520 cases were reported by June 16, 2012, a 1300% increase from the same time in 2011 (Debolt et al., 2012). The adult age group has been underdiagnosed with pertussis because of under-recognition of pertussis as a cough-related issue (CDC, 2012b). The problem is preventing and controlling the spread of the disease to infants and others at greatest risk for severe disease because of waning immunity. The CDC has reported a two- to threefold increase in pertussis outbreaks in the state of Mississippi from 2011 to 2012.

For the purpose of the study, the following questions were established to evaluate primary care provider attentiveness in preventing the outbreaks of pertussis:

1. Are adults 18 years and older being screened and offered the Tdap booster vaccination?
2. Are preteens between the ages of 10 and 12 years being screened and offered the Tdap booster vaccine?
3. Do primary care offices have and distribute education material about the Tdap immunization?

The sample for the study consisted of 200 charts collected from two adult and two pediatric primary care clinics in the state of Mississippi. Two of the clinics were from the northern area while the other two were from the southern area of Mississippi. In the

pediatric clinic, the charts were chosen based on the ages of 10 to 12 years. In the adult clinic, the charts were chosen based on 18 years and older. The data were collected using a data collection tool created by the researchers. The data were analyzed and compiled as percentages using descriptive statistics.

Interpretation of Findings

The researchers identified that the majority of males and females between the ages of 10 and 12 years were being offered or given the Tdap booster vaccine in this particular sample. The researchers believed that the administration of Tdap booster vaccine was higher in this age group due to the effect of the new Tdap guidelines. At the beginning of the 2012-2013 school year, all students entering public school systems in the state of Mississippi were required to have a Tdap vaccine prior to the start of school (CDC, 2012b). However, the adults in the primary care demonstrated that 53% were being screened, yet only 21% were vaccinated. The researchers believe that the reason for the difference in Tdap vaccine rates in adults is due to the need for education. The challenge would be educating the middle-aged and elderly adults about the benefits of the vaccine, its effectiveness, and its safety.

The researchers reviewed several literature studies pertinent to the research study. This literature review aided in providing background and suggestion in the technique the research was done. Hajia et al. (2012) revealed diagnostic tools that can accurately assist in screening for pertussis in individuals who are difficult to diagnose. These researchers used the Polymerase Chain Reaction (PCR). The findings concluded that the PCR method is verified to be sufficient, stable, and able to provide reproducibility of results when tested. Hajia et al.'s study was informative; however, these researchers were

unable to use the study in the current research. The study took place in a primary care setting and the diagnostic tool and technique mentioned in Hajia et al. (2012) are not a common procedure used in screening for pertussis.

Rossi-Foukes et al.'s (2010) study revealed the lack of knowledge by healthcare providers in regard to diagnosing and preventing the spread of pertussis. This study aided in determining that healthcare providers' knowledge has a big impact on the awareness and detention of pertussis in adolescent and adults. The study also stressed that effective methods of prevention and treatment of pertussis will occur if the knowledge gaps are restored. The findings of this study validate what the current studies have shown—that education is vital in improving vaccine rates.

Weston et al. (2011) indicated that the Tdap vaccine was safe and effective among the elderly. Weston et al. acknowledged that vaccinations provided two valuable benefits: (a) preventing an individual from contracting the disease and (b) preventing the infected individual from exposing the disease to other high-risk candidates such as infants. Weston et al. indicated a tremendous need to vaccine once the immunity of pertussis has diminished after 10 years. The study also supported the recommended guidelines of the CDC for screening and booster vaccine of all preteens between the ages of 7 and 12 years and adults 65 years and older. Weston et al. (2011) gave the researchers guidelines and confirmation that screening and immunization are vital in adults, especially adults 65 years and older.

The priority for the primary care provider to screen adult patients at every visit was studied by Gannon et al. (2012). The study focused on the lack of preventive health care in the family practice setting because of the focus on complex medical problems.

Gannon et al. developed a quality improvement curriculum and included all office staff members in the education of adult vaccine recommendations. The team approach increased the amount of adult vaccines given because each person in the office had the responsibility of screening patients. Gannon et al. (2012) encourage clinics in their area to use a quality team approach to improve the vaccination rates within their office setting.

Requirement of a Tdap vaccine before entering the sixth grade improved vaccination rates in 11- to 14-year-olds in New York State. Kharbanda et al. (2010) found that a mandate on the Tdap vaccine before interring the sixth grade increased the vaccination rates in preteens and adolescents 11 to 14 years old. The results from this study are important because Mississippi has enacted a similar mandate, which requires that all children have a Tdap vaccine before entering the seventh grade. The current researchers confirmed that the pediatric population is being screened and given the Tdap vaccination more than adults but revealed the need to improve adult immunizations. The nurse practitioner could be a catalyst in improving adult vaccinations by educating their office workers and their patients.

Carstensen et al. (2012) documented the safety and immunogenicity of the Tdap vaccine when given to healthy adults. Since the ACIP recommends all adults 18 years and older receive a Tdap booster once in place of a Td immunization to protect against pertussis (ACIP, 2006). Establishment of the safety of the vaccine will give the nurse practitioner an education tool to teach patients the importance of the vaccine. The study complements the current study because these researchers can use the knowledge to increase knowledge of other providers on the safety of the vaccine.

The nurse practitioner can use all the information from the researchers' study and the review of literature to increase their knowledge and practice skills on vaccination schedules for preteens, adolescents, and adults. Nurse practitioners can have vaccination information programmed into the electronic medical records at their offices to increase compliance with screening and giving vaccinations.

Limitations

Limitations identified in the study that could have affected the outcomes were as follows. First, the sample collected was small in size. Only 200 charts were used in the study, which is a small number and may have significantly decreased the reliability of the results. Second, one of the clinics evaluated did not have a system for charting recommendations or education on Tdap. Some patients may have received the recommendation to receive the Tdap booster, but the information may not have been documented in the chart.

Implications and Recommendations

There are a few implications for future research in the area of the Tdap vaccine. It would be interesting to see if the Tdap vaccine rate decreases after the new regulation that Medicaid will not cover the cost of the vaccine. Another area for future research would be a study using a larger and more diverse population. Increasing the sample size and expanding the geographical area for data collection would result in a more thorough and accurate result. The influence of this study on the researchers has increased their interest in vaccine administration and education.

The researchers' recommendation for this study is to urge primary care providers to promote more education about the need for the Tdap vaccine to be repeated. Providers

might consider building a reminder into the electronic medical record program to ask patients about the Tdap vaccine. This approach would give healthcare providers the opportunity to educate the patient about the Tdap booster. The providers could also possibly educate the community by contacting the wellness center director about organizing groups, presenting talks, and sharing information pamphlets.

Contribution to Nursing Theory

The nursing theory used in this research study was Nola Pender's Health Promotional Model. Pender's theory implies that one behavior can result in the level of participation in self-health promoting behaviors. This theory is important to the current research study because with self-health promoting beliefs, such as the Tdap vaccine, pertussis can be prevented. This theory bases its importance on the patient's knowledge, experience, and beliefs in order to participate in health-promoting behaviors effectively. Actively endorsing Pender's theory of health promotion by educating and offering immunization is a means to increase the patient's behavior of illness prevention. After applying this theory to the research, it was clear that healthcare providers are the main foundation in promoting and providing prevention against life-threatening diseases such as pertussis.

Conclusions

The results suggest that healthcare providers in Mississippi are fairly consistently recommending and administering the Tdap vaccine to eligible pediatric males and females. However, there is a need for improvement in the adult population. The primary adult group that would benefit from being vaccinated was not based on lack of education on prevention regarding the importance of the Tdap booster vaccine.

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APPENDIX A

Approval of Mississippi University for Women

Institutional Review Board

Following is a summary of documents needed for use in the review.
Form A- Identification of Investigators and Brief Review of Proposed Research (submitted by the researcher)
Form B- Evaluation Form for Committee Review (submitted by the researcher)
Form C- Sample of Informed Consent (submitted by the researcher)
Form D- Guidelines for the Protection of Human Rights (used by the Review Panel)
Form E- Definition of Terms (given to the researcher)

FORM A

MISSISSIPPI UNIVERSITY FOR WOMEN
INSTITUTIONAL REVIEW BOARD

IDENTIFICATION OF INVESTIGATORS AND BRIEF DESCRIPTION OF
INVESTIGATORS AND BRIEF DESCRIPTION OF
PROPOSED RESEARCH REVIEW

TITLE OF STUDY:
Tdap screening and pertussis prevention throughout the age span

PRINCIPAL
INVESTIGATOR: Thu Tran RN BSN, Cara Harris RN BSN

_____
(Signature)

DEPARTMENT_____(Date)_____

RESEARCH ADVISOR: Dr. Patsy Smyth

_____
(Signature)

Instructions: In the space below (use additional sheets where necessary):

1. Briefly describe the purpose and nature of the present research proposal. State what, if any, benefit is to be gained by the subject(s) or what information is to be added to the general body of knowledge as a result of this research.
The purpose of the project is to determine if healthcare providers are recommending or administering diphtheria toxoid and acelluar pertussis (Tdap) to people ages 10-12 and 18 and older. Pertussis is a contagious disease, which has seen a substantial rise in epidemic proportions during 2011. The diphtheria toxoid and acelluar pertussis (Tdap) vaccine is the most effective protection strategy for preventing the disease.

2. List all procedures to be used on human subjects with a description of those you consider beyond already established and accepted techniques.
The research project is based on a retrospective chart review by the researchers; therefore human subjects will not be tested or experimented on, only used to obtain information in the study.

3. Describe the necessary safeguards to be applied to protect the subject.
The information obtained will not include any identifiable characteristics such as names of the subjects from the chart review. The only information that will be used will be the subjects' age, race, and sex. There will be no physical contact with the patient, parent, or guardian, f the information obtained. Variables will be used on the data collection worksheet to represent the patients' age, race, gender; what type of healthcare provider was used (medical doctor or nurse practitioner); and what type of insurance was used. since this is a retrospective chart review. A Data Collection Instrument will be used to keep track of the information obtained. The with the patient, parent, or guardian, since this is information will

be entered into a computer for statistical analysis. Collected data will be stored onto a portable flash drive, which only the researchers and researcher advisor could access by a password. The data collection worksheet will be shredded once the information has been saved onto the flash drive. The drive will be kept secure, and lock throughout the project. After research is complete and paper written with approval all stored data will be destroyed.

4. State whether or not you consider the subject to be "at risk." If you consider the subject to be "at risk", in what respect do the potential benefits to the subject or contributions to the general body of knowledge outweigh the risks?
Not applicable.

5. If you consider the subject to be "at risk," state exactly what you tell him in lay language to obtain informed consent relative to each procedure wherein he is "at risk." This must be a form that is given or read to the subject particularly for this purpose. If subjects are children what will be told to parent or legal guardian?
Not applicable.

6. State from whom documentation of informed consent will be obtained.
We plan to obtain consent from the two clinics the chart reviews will take place in Northeast and Southwest Mississippi.

7. Attach copies of all questionnaires to be used.

FORM B

EVALUATION FORM FOR INSTITUTIONAL REVIEW BOARD

Date Submitted to Committee: _____

Title of Investigation Tdap screening and pertussis prevention throughout the age span

Principal Investigator: Thu Tran; RN BSN, Cara Harris RN BSN

Funding Agency: Funding is not necessary for this research project

Funding Agency Grant Number: (NIH, BEH, when applicable): Anticipated number of human subjects to be studied (when applicable): Not applicable

Projected duration of investigation: January 14, 2013-July 31, 2013

Age range of human subjects: The retrospective chart review will be on subjects 11 to 65 years of age

Any mental or physical impairment present in the subjects: The retrospective chart review will not include any known people with mental or physical impairments. We are not interviewing or having any physical contact with the participants.

Criteria for subject selection: Preteens of the age of 11 and adults age 65 years and older.

Potential for beneficial effect to human subject arising from investigation: The human subjects will not directly receive benefit from the research since the information will be obtained from a chart review

Potential adverse effects (psychological, behavioral and physiological) arising from investigation: Since the information will be obtained from chart reviews, the subjects will not be inflicted with psychological, behavioral, and physiological effects of the project

Potential or established side effects of drugs used in investigation: Since this is a retrospective chart review, there will not be drugs involved in the investigation

Brief justification of research where immediate benefit to specific human subject is absent or unknown: Since this is a retrospective chart review, specific human subjects involved in the study will not receive any benefits. The information obtained during the research project may help those in the future.

For On-Going Investigations Only. Number of subjects studied: 200 chart reviews will be audited from 1 Northeast and 1 Southwest Mississippi clinics

Documented adverse psychological, behavioral, physiological and pharmacological

effects of study: This is a retrospective chart review, therefore psychological, behavioral, physiological, and pharmacological effects will not be endured by the participants.

Precautions used to detect, prevent, minimize or reverse adverse side effects:
No precautions were utilized, since this was a retrospective chart review

Change in methods or procedures (when applicable):
Not applicable

Change in intent, direction or scope of research (when applicable):
Not applicable

FORM C

SAMPLE OF INFORMED CONSENT
INSTITUTIONAL REVIEW BOARD

1.State exactly what you will tell subject, parent/guardian.
This is a retrospective chart review. We will obtain consent from 2 Mississippi clinics to obtain the information in the research project.

2. State how you will obtain documentation of informed consent. (Submit sample document). See appendices

FORM D

GUIDELINES FOR THE PROTECTION OF HUMAN RIGHTS INSTITUTIONAL REVIEW BOARD

Review Form D

If "no" checked, please explain in writing and attach.

1. Right to Privacy YES / NO
Yes
1.1 Obtained free and informed voluntary written consent. See appendices
1.2 Provide for anonymity Yes
1.3 Information obtained held in confidence Yes
1.4 When a reasonable possibility exists that others may obtain access to information, plans for protecting the confidentiality are explained to the subject. Yes

2. Right to Self-determination

2.1 Voluntary consent obtained without overt or covert coercion. Yes
2.2 Deception of subject or concealment of purpose avoided. Yes
2.3 When concealment is necessary, it is communicated to the subject and a contract is made to inform the subject as the design permits. Not applicable. Since this is a retrospective chart review, concealment is not necessary. There will not be any contact or communication with the subjects involved in the study.
2.4 Explanations are not ambiguous and the terminology used is appropriate to the subjects level of understanding. Yes
2.5 Subject free to withdraw consent at any point and informed of such. Yes
2.6 Obtained third party written consent if necessary. Yes

3. Rights of Minors and Legally Incompetent Persons
3.1 If a minor, informed written consent from parents required and obtained. No. Since this is a retrospective chart review, we will obtain written consent from the clinics where the information is being collected for the study.
3.2 If legally incompetent, informed written consent from legal guardian required and obtained. No. Since this is a retrospective chart review, we will obtain written consent from the clinics where the information is being collected for the study.
3.3 Supplemental written consent obtained from minor when minor has capacity to comprehend implications of study. No. Since this is a retrospective chart review, we will obtain written consent from the clinics where the information is being collected for the study.

4. Right of Conservation of Personal Resources
4.1 Time, freedom from constraint, and personal resources are not abused. Not applicable. Since this is a retrospective chart review, the researchers will have no contact with the participants.
4.2 Subject is informed about the nature, extent, and possible consequences of study. No. Since this is a retrospective chart review, the researchers will have no contact with the participants.
5. Right to Freedom from Arbitrary Hurt 5.1 Subject protected from arbitrary mental and/or physical suffering as a result of study. Yes

6. Right to Freedom from Intrinsic Risk of Injury
6.1 Subject has full information about proposed investigation if there is a risk of emotional and/or physical injury. Not applicable. Since this is a retrospective chart review, the researchers will not have any contact with the participants. The results will be given to the healthcare providers participating in the study.

7. Additional Safeguards
7.1 Deviation from any of the above principles. No. There will be no deviation from the above principles.
7.2 Evidence demonstrated that appropriate expert advice has been received that it is acceptable to deviate. No. Since this is a retrospective chart review, there will not be any reason to deviate.
7.3 The researcher has demonstrated that research assistants have been, or will be trained in the ethics involved in carrying out the research design. Yes.

_____ _____
Vice President for Academic Affairs Date

REFERENCE: ANA Ethical Guidelines APA Ethical Principles University of Michigan, Guidelines for the Protection of Human Rights University of Indiana, Guidelines for the Protection of Human Rights

FORM E

DEFINITIONS OF TERMS USED BY INSTITUTIONAL REVIEW BOARD

Investigator*:
A graduate student enrolled in or a faculty member who desires to conduct research with human rights who
1. Is representing himself/herself as a student or faculty member.

Research 1
Any organized research, research, potentially publishable to include theses and funded research.

Subject 2
Any individual who may be "at risk" as a consequence of participation as a subject in research.

At Risk 2
Any individual is considered "at risk" if he may be exposed to harm physical, psychological, sociological, or other as a consequence of any activity which goes beyond the application of those established and accepted methods necessary to meet his needs.

Informed Consent 2
Informed consent is the agreement obtained from a subject, or from his authorized representative, to the subject's participation in an activity.

1.The basic elements of informed consent are:
2.A fair explanation of the procedures to be followed, including an identification of those which are experimental;
3.A description of the attendant discomforts and risks;
4.A description of the benefits to be expected;
5.A disclosure of appropriate alternative procedures that would be advantageous for the subject;
6.An offer to answer any inquiries concerning the procedures;
7.An instruction that the subject is free to withdraw his consent and to discontinue participation in the study or activity at any time.

*Any other person conduction research who desires human rights review by this Committee.

1- Mississippi University for Women Faculty Council, March 25, 1980.
2- United States Department of Health, Education, and Welfare: Policy on Protection of Human Subjects, 1971.

Timeline

Conceptual Phase- August 2012-December 2012

- Problem identification
- Literature review
- Theoretical framework

Design/Planning Phase- December 2012-January 2013

- Research design
- Population specification
- Sampling plan
- Data collection plan

Empirical Phase- February 2013-April 2013

- Collection of data
- Data preparation

Analytic Phase- May 2013

- Data Analysis
- Interpretation of results

Dissemination Phase-July 2013

- Presentations of reports
- Utilization of findings

Mississippi University
for Women
A Tradition of Excellence for Women and Men

Provost and Vice President for Academic Affairs
1100 College St. MUW-1603
Columbus, MS 39701-5800
(662) 329-7142
(662) 329-7141 Fax

www.muw.edu

February 18, 2013

Patsy Smyth, DSN
Mississippi University for Women
College of Nursing and Speech-Language Pathology
MUW – 910
Columbus, Mississippi 39701-5800

Dear Dr. Smyth:

I am pleased to inform you that the members of the Institutional Review Board (IRB) have reviewed the following proposed research and have approved it as submitted:

Name of Study:	Tdap Screening and Pertussis Prevention Throughout the Age Span
Investigator(s):	Cara Harris and Thu Tran
Research Faculty/Advisor:	Patsy Smyth

I wish you much success in your research.

Sincerely,

Dan Heimmermann, Ph.D.
Provost and Vice President for Academic Affairs

DH/jh

pc: Tammie McCoy, Institutional Review Board Chairman

APPENDIX B

Letter of Consent for Participation in Research Study

Date: February, 2013
Name of Clinic:
Clinic Address:
City, State, Zip Code:

We are graduate students in the family nurse practitioner program at Mississippi University for Women in Columbus, MS. As a program requirement, we are conducting a retrospective chart review to assess screening for Tdap immunization as a booster vaccine given to 10-12 years olds. We will be assessing documentation for screening and Tdap vaccination to preteens age 10-12. The students that are participating in this research project include: Cara Harris and Thu Tran.

Your participation will involve granting us the privilege of reviewing medical records of your clients with dates of birth between 2001 and 2003. As researchers, we understand that we must maintain the confidentiality of all information collected from the charts. We agree to refrain from discussing or disclosing any information regarding your clients. Each researcher has received Human Insurance Portability and Accountability (HIPAA) training and certification. The study includes a retrospective chart review following HIPPA guidelines and will not involve human participants. The chart reviews will be recorded on a Data Collection Worksheet then entered into a computer data sheet. This information will only be accessible by the researchers and their faculty researcher advisor. After completion of the project, all physical data will be destroyed appropriately. The results of this study may be published; however, neither names nor patient information will be identifiable.

Your participation in this study is strictly voluntary. The possible benefit of your participation is that the research project will serve as a quality assurance measure for you. The amount of time required for us to review charts and collect data will be approximately one month. After the research project is complete, we will provide you with the results from the study.

If you have any questions concerning this research study, please call Cara Harris (228) 209-2606, Thu Tran (228) 235-9550 or contact the chair of our research committee, Dr. Patsy Smyth (662) 889-8384. In addition, you may withdraw your consent and participation in this study at any time by contacting one of us or the chair of our research committee.

By completing and signing the attached consent form, you are indicating that the study has been explained to you and that you agree to participate in the study.

Sincerely,

Cara Harris

Thu Tran

****

I have read this letter of consent and have been given the opportunity to ask questions. I give my consent to participate in the above study.

_____ _____

Clinic Manager Signature Date

****

I have read this letter of consent and have been given the opportunity to ask questions. I give my consent to participate in the above study.

_____ _____

Clinic Manager Signature Date

APPENDIX C

Data Collection Worksheet

Chart# _____

1. Age: _____

2. Gender: (0) Male (1) Female

3. Ethnicity: (0) African American (1) Caucasian (2) Other _____

4. Is the patient screened for the need of Tdap Vaccine?

5. Has vaccine been given? Dates of administration of pertussis–containing vaccine

_____

6. Does the clinic have Tdap and Pertussis educational information?